Position Details

- **Title:** Sterilization Subject Matter Expert Consultant
- **Location:** Remote
- **Travel:** Up to 25%
- **Type:** Consideration will be given to part-time and full-time
- **Experience Required:** 6-10 years in medical device sterilization and microbiology
- **Reports to:** CEO

Job Summary

The primary responsibility of this position is to assist clients with validation of sterilization processes, biocompatibility testing, cleanroom validation, and cleaning/disinfection validation for reusable medical devices within a Quality Management System framework. This position requires independent utilization of sound validation techniques and strategies, including but not limited to ethylene oxide, radiation, and steam sterilization methods, understanding of principles of cleanroom validation and validation of disinfection and cleaning methods for reusable devices. Must possess a keen understanding of industry standards and guidance to assist clients with root cause failure investigations in sterilization, and biocompatibility. The Consultant must interact with other consultants, clients, laboratories, and experts outside QA Consulting to communicate and implement company and client objectives. Client and project management skills are required.

Principal Duties and Responsibilities

- Understanding of microbiology principles (especially ethylene oxide and radiation sterilization validation methodologies, biocompatibility, clean room operations and validation) and applicable ISO/AAMI/ANSI standards and USP/ASTM test methods
- Provide technical support to sterilization, cleaning, biocompatibility, and cleanroom projects using microbiological theory and practice. Offer and implement original solutions to new problems that facilitate successful completion
- Use applicable standards, procedures, and academic understanding of microbiology principles to accomplish tasks.
- Implement processes and procedures and conduct analyses to sustain and improve the Quality Management Systems and/or Microbiological Systems of QA Consulting's clients. Examples include analysis of sterilization or biocompatibility test failures, establishing alert/action levels for cleanroom monitoring and bioburden testing. Additional examples include conducting and documenting risk analyses to implement alternatives to batch testing for endotoxin monitoring, writing procedures including cleanroom monitoring, bioburden monitoring, and analyzing data to establish parametric release for EO sterilization processes.
- Write technical protocols/ reports using relevant standards and analyze data to establish specifications
- Assist with quoting of microbiology projects including bioburden, cleanrooms, cleaning and sterilization validations, and biocompatibility assessments
- Project manage all stages of sterilization and cleaning validations including protocol development, laboratory management, and report writing.
- ***This is not an exhaustive list of duties or functions***

Knowledge, Skills and Abilities

- Extensive knowledge in the principles of sterilization and microbiological procedures for sterile medical device manufacturing
- Must demonstrate competence in the medical device quality system regulations 21 CFR820, ISO 13485, and ISO 14971
- Able to apply quality tool techniques such as: design controls, quality system auditing, inspection methods, statistical sampling plans, gauging studies, design verification and validation, and process validation
- Ability to apply mathematical concepts such as statistical inference and probability
- Understanding of microbiology principles (EO, radiation, and steam sterilization and microbiology/methodologies, biocompatibility, cleanroom validation) and applicable ISO/AAMI/ANSI standards and USP/ASTM test methods
- Ability to apply logic, creativity, and scientific thinking to a wide range of intellectual and practical problems
- Time management and strong written and verbal communication both to QA Consulting staff and the clients
- Demonstrates ownership for the integrity of work
- Must be able to manage projects and work with team members to complete tasks on time and within budget

Education

- Bachelor's degree in Microbiology or related scientific discipline is required
- Master's degree preferred

Characteristics

- Deadline driven
- Able to work efficiently, independently and as part of collaborative team
- Proactive communication skills